HALO^{FLEX} System

Model 1190A-115A (Domestic)

Model 1190A-230A (International)

USER'S MANUAL

Manufactured By

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1 INTRODUCTION

The System presented in this User's Manual consists of the HALO^{FLEX} Energy Generator with HALO^{FLEX} Output Cable, disposable single-use HALO^{360+} Ablation Catheter or HALO^{90} Ablation Catheter, disposable single-use HALO^{360} Sizing Balloon or HALO^{360+} Sizing Balloon and an optional accessory HALO^{FLEX} Footswitch.

The HALO^{FLEX} Energy Generator supplies up to 300 watts of radiofrequency (RF) power at 460 kHz in a bipolar mode under power control while continuously monitoring and displaying power, energy density, and balloon inflation pressure. Energy density is displayed to allow equivalent energy delivery to the range of HALO^{360+} Ablation Catheter diameters and the HALO^{90} Ablation Catheter. An inflation system is also included in the HALO^{FLEX} Energy Generator.

For the user's convenience, the HALO^{FLEX} System may be referred to in this User's Manual as the "System," the HALO^{FLEX} Energy Generator may be referred to as the "Energy Generator," the HALO^{FLEX} Output Cable may be referred to as the "Output Cable," the HALO^{360+} Ablation Catheters may be referred to as "Balloon Based Ablation Catheters," the HALO^{90} Ablation Catheter may be referred to as "Non Balloon Based Ablation Catheter," the HALO^{360+} Ablation Catheter and HALO^{90} Ablation Catheters may be referred to jointly as "Ablation Catheter," the HALO^{360} Sizing Balloon or HALO^{360+} Sizing Balloon may be referred to as the "Sizing Balloon," the Ablation Catheters and Sizing Balloons may be referred to jointly as "Catheters" or "Disposable Devices" and the optional HALO^{FLEX} Footswitch may be referred to as the "Footswitch." The Footswitch Unit houses 2 Foot Pedals, RF POWER ON/OFF – blue pedal and AUTO INFLATION – gray pedal, and may be referred to as "Foot Pedal."

This User's Manual provides a description of the Energy Generator, Output Cable, Disposable Devices, Footswitch, the Energy Generator's controls and displays, and a sequence for its operation.

This User's Manual also supplies other information of importance to the user. This manual is intended as a User's Manual only. Do not operate the System before thoroughly reading this manual or reading the IFU for the specific Ablation Catheter or Sizing Balloon being used.

2 INDICATED USE

The HALO^{FLEX} Energy Generator is indicated for use for the coagulation of soft tissue.

The HALO^{FLEX} System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, Angiodysplasia, Gastric Antral Vascular Ectasia and Radiation Proctitis.

EU, Canada:

The HALO^{FLEX} System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to Barrett's Esophagus.

3 CONTRAINDICATIONS

This User Manual should be used in conjunction with the Instructions for Use provided with each type of disposable device. See Instructions for Use provided with the disposable device for the Contraindications.

4 WARNINGS AND PRECAUTIONS

 The safe and effective use of RF energy is highly dependent upon factors under the control of the operator. There is no substitute for a properly trained medical staff. It is important that the operating instructions supplied with the Energy Generator be read, understood and followed before use.

4.1 WARNINGS

4.1.1 Energy Generator

- Do not operate the Energy Generator before thoroughly reading this manual and the IFU for each disposable device.
- Do not remove the cover of the Energy Generator, as there is a potential for electrical shock. Refer to authorized personnel for service. Do not use the generator if significant damage to the cover or front panel is detected as there is a risk of electrical shock.
- Do not use this device in the presence of flammable anesthetics; other flammable gases; near flammable fluids such as skin prepping agents and tinctures; flammable objects; or with oxidizing agents. Observe appropriate fire precautions at all times.
- Do not use this device in Oxygen enriched atmospheres, Nitrous Oxide (N_2O) atmospheres, or in the presence of other oxidizing agents. While using this device during a procedure, the patient should not be allowed to come into direct contact with grounded metal objects such as the surgical table frame, the instrument table, etc.
- When the Energy Generator is activated, the conducted and radiated electrical fields may interfere with other electrical medical equipment.
- It is necessary to use the supplied hydrophobic filter (included in all Balloon Catheter's packaging), placed between the pneumatic connector located at the proximal end of both the Sizing Balloon and Ablation Catheter and the pneumatic connector line on the Output Cable to ensure fluids are not aspirated into the Output Cable in the event of a balloon leak. If the catheter is used without the filter, and a balloon leak occurs, inspect the clear tubing portion of the connecting Output Cable for traces of fluid. If fluid is detected, discontinue the use of the Output Cable and order a replacement.
- Only inflate all HALO Balloon Catheters using the inflation system incorporated into the Energy Generator.
- If the Energy Generator displays an E95 or C56 Operational Code, this is most likely caused by an air leak in the system. If the E95 or C56 Operational Codes are observed, under endoscopic visualization, manually deflate the balloon using a syringe via pneumatic connector at the proximal end of Ablation Catheter, remove and replace the catheter.

- Visual endoscopic confirmation of complete balloon deflation must be performed prior to attempting to reposition or remove a Balloon Based Ablation Catheter or Sizing Balloon.
- Do not deliver RF energy in areas containing surgical staples. The presence of metallic staples may disturb the treatment pattern and may lead to complications.
- Needle monitoring electrodes are not recommended for use with this equipment.
- Patient monitoring systems used with this equipment should incorporate high frequency current-limiting devices.
- The Output Cable should be placed as to avoid unnecessary contact with patient leads or leads from other patient-connected equipment. Do not use the Output Cable if the insulation is damaged to prevent the risk of electrical shock.
- Failure of the Energy Generator could result in an unintended power output increase.
- Place any monitoring electrodes as far as possible from the surgical electrodes when RF surgical equipment and physiological monitoring equipment are used simultaneously on the same patient.
- Electrosurgery should be used with caution in the presence of internal or external pacemakers. Interference produced with the use of electrosurgical devices can cause devices such as a pacemaker to enter an asynchronous mode or can block the pacemaker entirely. Consult the pacemaker manufacturer or hospital Cardiology department for further information when use of electrosurgical devices are planned to be used in patients with cardiac pacemakers.
- This equipment is intended to be used by healthcare professionals only.
- This equipment has been tested and complies with the limits for medical devices to the IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.
- This equipment may cause radio interferences or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment or shielding the location. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.
- Generator contains a 3.3V Lithium Battery (Ref designator BTI) and a 5A 250V μ Fuse (Ref designator FI). These parts may only be replaced by BÂRRX authorized service personnel. There are no user-serviceable parts in this device. Refer servicing to qualified BÂRRX Medical, Inc. personnel by contacting BÂRRX Medical, Inc. at 888-662-2779 or 408-328-7310.

4.1.2 **Ablation Catheters**

- See HALO^{360+} Ablation Catheter or the HALO^{90} Ablation Catheter Instructions for Use (IFU).
- Do not use the HALO^{360+} Ablation Catheter or HALO^{90} Ablation Catheter if the catheter insulation is damaged, as there is a risk of electrical shock.

4.1.3 **Sizing Balloon**

- See HALO^{360+} Ablation Catheter and Sizing Balloon IFU.

4.2 PRECAUTIONS

4.2.1 **Energy Generator**

- This System cannot be used at an elevation greater than 7000 feet (2,134 meters) above sea level or lower than 300 feet (91 meters) below sea level.
- Do not activate the Energy Generator until the Ablation Catheter is properly positioned in the patient.
- The activation tone and light are important safety features. Do not obstruct the activation light. Do not disable the audible tone.
- Use only the provided HALO^{FLEX} Footswitch model with the Energy Generator.
- The main Power cord of the Energy Generator MUST be connected to a properly grounded receptacle. Extension cords and/or adapter plugs MUST not be used.
- Do not wrap the Output Cable around metal objects. Wrapping cables around metal objects may induce hazardous currents.
- Disconnect all cables after use.

4.2.2 **Ablation Catheters**

- See HALO^{360+} Ablation Catheter or the HALO^{90} Ablation Catheter Instructions for Use (IFU).
- Ablation Catheter electrodes must be kept away from patient and user when not in use.

4.2.3 **Sizing Balloon**

- See HALO^{360+} Ablation Catheter and Sizing Balloon Instructions for Use (IFU).

5 INSTALLATION

Inspect the Energy Generator and Output Cable for any signs of physical damage to the front and/or back panel, chassis, cover, the Output Cable or any insulation. If any physical damage is found, DO NOT USE THE UNIT. Contact BÂRRX Medical, Inc. for a replacement. BÂRRX Medical, Inc. must approve all returns.

5.1 Preparing the System for Use

The Energy Generator may be placed on a mounting cart or on any sturdy table or platform. It is recommended that carts have non-conductive wheels. Refer to hospital procedures or local codes for detailed information.

Provide at least four to six inches of space around the sides and top of the Energy Generator for convection cooling. Do not prop the Energy Generator on top of anything that will interfere with its underside clearance. Do not store items directly under the Energy Generator. Do not stack Generators. Under continuous use for extended periods of time, it is normal for the top and rear panel to be warm.

5.2 Mains Power Cord

The Energy Generator is shipped with an approved hospital grade mains power cord.

Do not use extension cords or three-prong to two-prong adapters. The mains power cord assembly should be periodically checked for damaged insulation or connectors.

5.3 Energy Generator Cleaning and Disinfection Instructions

Use a mild detergent and damp cloth to clean the Energy Generator cover, front panel, and power cable. The Energy Generator is not sterilizable. Do not allow fluids to enter the Energy Generator chassis. The Energy Generator may be disinfected using a standard hospital alcohol solution applied with a cloth or by wiping down equipment with sodium hypochlorite 500 ppm wipes; leaving it in contact with all surfaces for 10min; then using a damp cloth clean with neutral detergent. Do not expose the metal pins of the connector to the sodium hypochlorite wipes in order to prevent corrosion. Do not spray or pour liquids directly on the unit.

Figure 1A - HALO^{FLEX} Energy Generator Front View with Footswitch

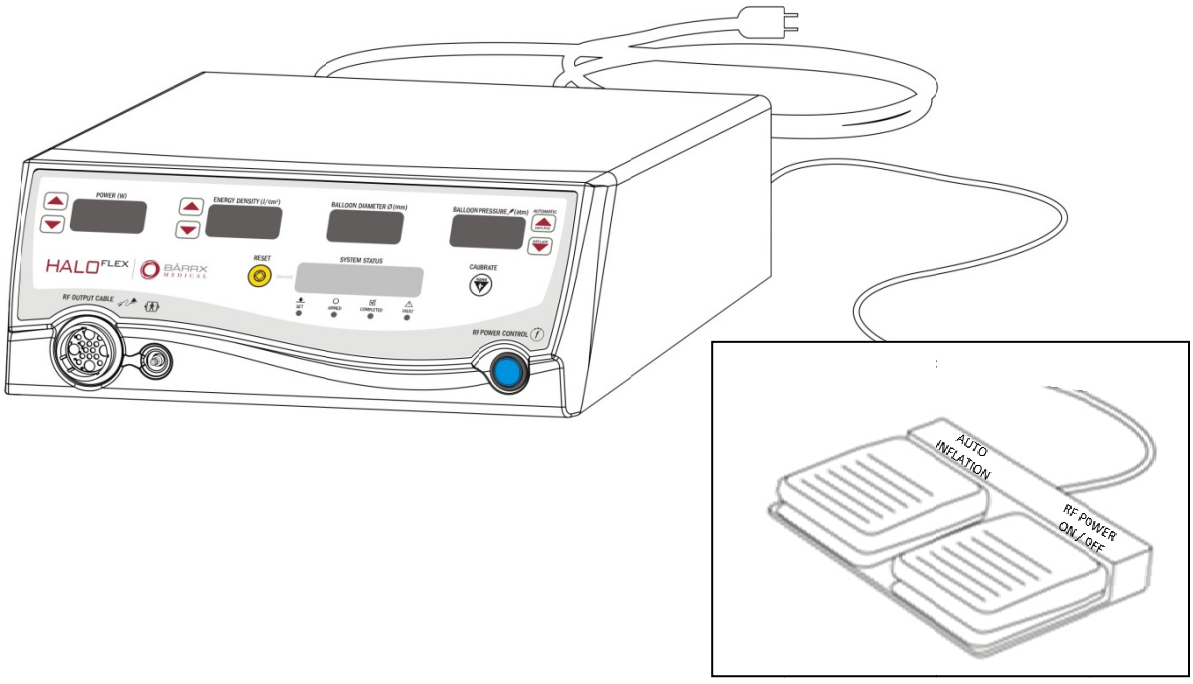


Figure 1B - HALO^{FLEX} Energy Generator Rear View (Model 1190A-115A)

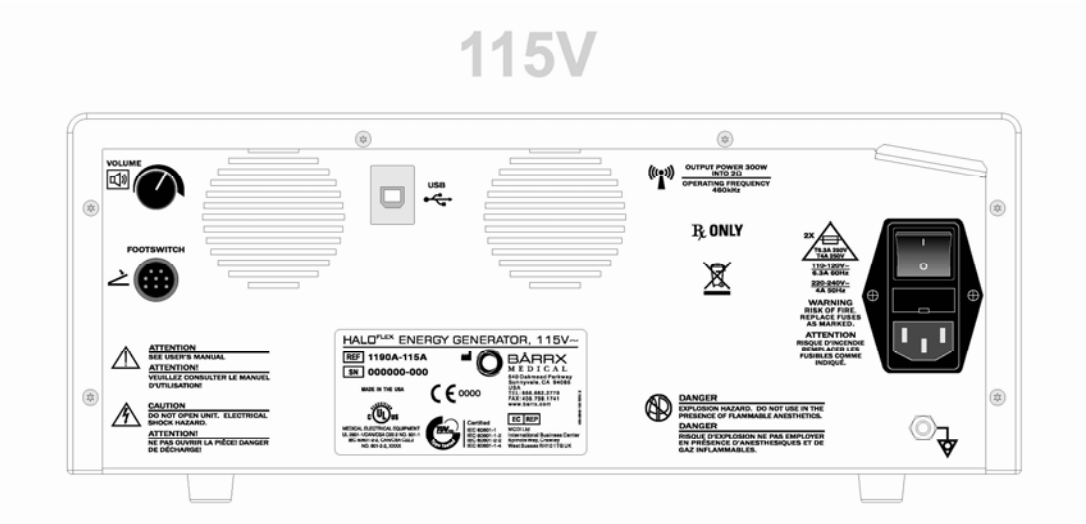


Figure 1C - HALO^{FLEX} Energy Generator Rear View (Model 1190A-230A)

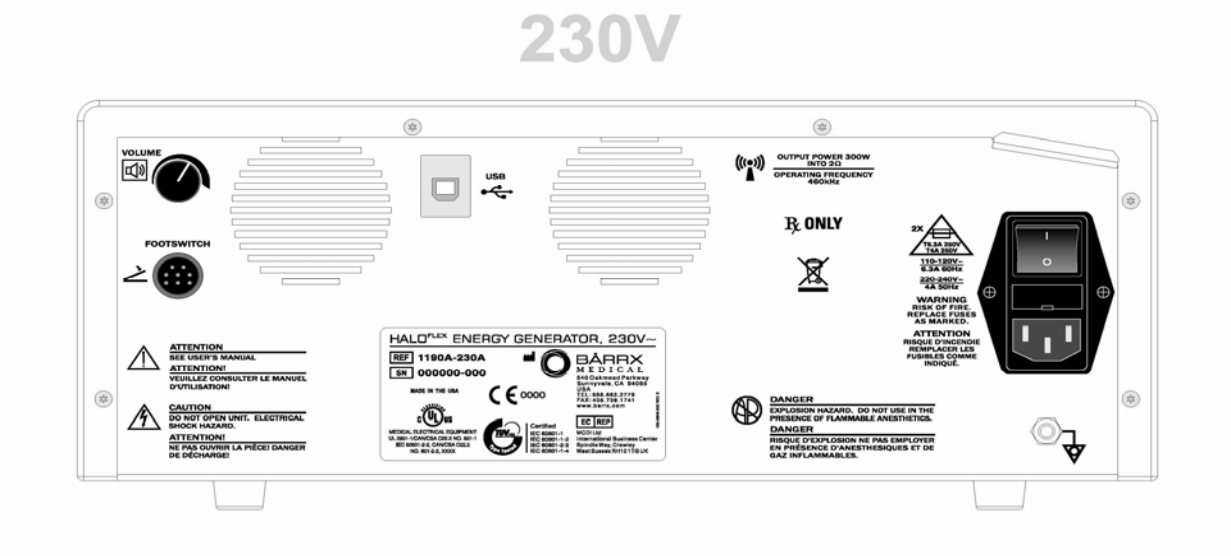
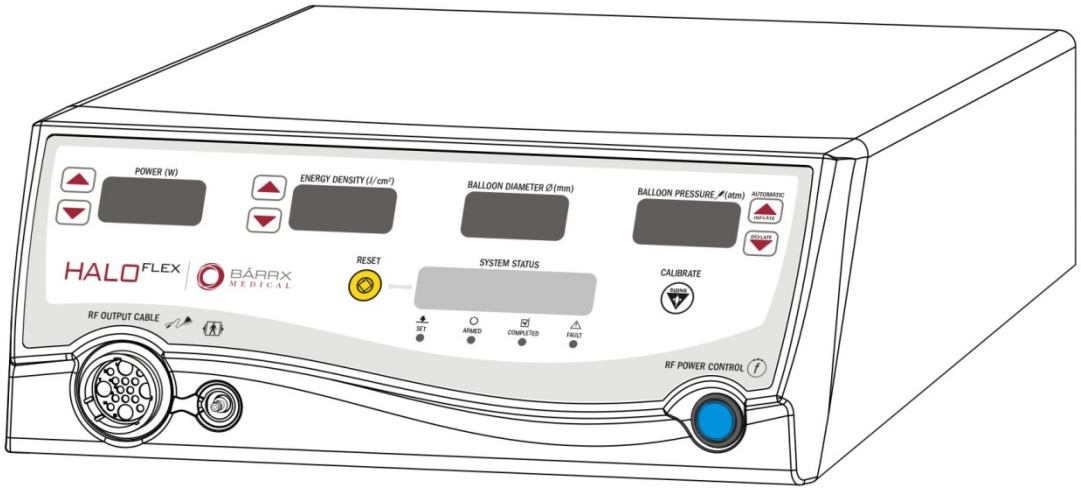


Figure 1D – HALO^{FLEX} Energy Generator Front View
(Models: 1190A-115A & 1190A-230A)

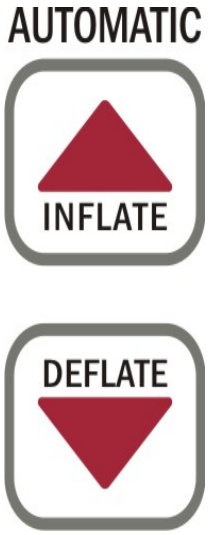


5.4 HALO^{FLEX} Energy Generator Controls

A description of the control buttons and their functions are given below. Please refer to Figures 1A through 1D for the location of each item on the generator.

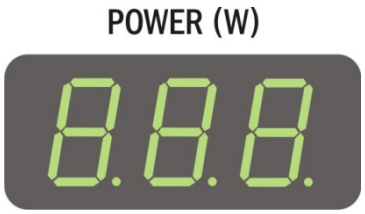
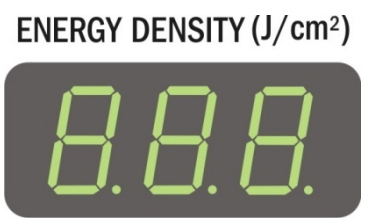
5.4.1 Energy Generator Buttons

Graphic	Button Description
	**Up ▲** Increases the value displayed in the adjacent numeric LED display. A single depression of the key increases the value by one unit. Continuous depression increases the display to the maximum allowable value.
	**Down ▼** Decreases the value displayed in the adjacent numeric LED display. A single depression of the key decreases the value by one unit. Continuous depression decreases the display to the minimum allowable value.

Graphic	Button Description
	**RF POWER CONTROL –** Starts and stops the output of radiofrequency energy. **The switch flashes blue when the balloon is inflated and/or when energy is ready to be delivered**. The switch is **constantly illuminated** with a blue lamp when **RF energy is being delivered.** The switch initiates RF energy delivery to **HALO^{360+}** or **HALO^{90}**Ablation Catheter electrodes.
	**AUTOMATIC INFLATE OR DEFLATE CONTROL BUTTONS –** Allows inflation or deflation of the **HALO^{360+}** Ablation Catheter and Sizing Balloon. (N/A to **HALO^{90}**Ablation Catheter). Pressing of the ▲ Button once causes the balloon inflation system to inflate the Ablation Catheter or the Sizing Balloon to the MAXIMUM allowable pressure. Pressing of the ▼ Button causes the balloon inflation system to fully deflate the Ablation Catheter or Sizing Balloon. Note: **HALO^{360+}**Ablation Catheter, automatically deflates after the delivery of RF energy is completed.
	**RESET Button –** Clears Operational Codes and recoverable codes. Does not clear unrecoverable codes.

Graphic	Button Description
CALIBRATE 	**CALIBRATE Button –** Used to calibrate the Sizing Balloon. Calibration is performed on the Sizing Balloon to establish measurement accuracy.

5.4.2 Energy Generator Displays (Green Color LEDs)

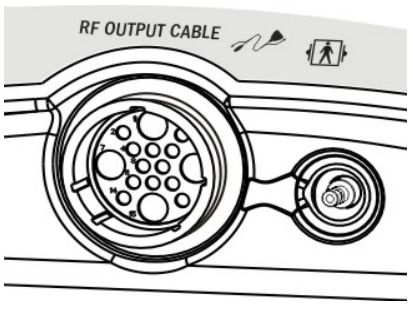
Graphic	Description
	**POWER Display–** During CATHETER CONNECTED Mode, displays the maximum RF power that can be applied. During RF POWER ON Mode, there is no display. **Range: 1 to 300 W**
	**ENERGY DENSITY Display –** Displays the maximum energy density that can be applied, as set by the Energy Generator. Energy density is calculated based on desired amount of energy divided by the area of Ablation Catheter electrode selected. **Range: 1.0-99.9 J/cm^2**
	**BALLOON DIAMETER Display –** Indicates diameter of organ as measured by the Sizing Balloon. **Range: 1 to 99.9 mm**
	**BALLOON PRESSURE Display –** Indicates pressure level in the Automatic Inflation system. Negative pressure (i.e. a vacuum) is displayed as "LO". **Range: LO to + 9.99 atm**
	**SYSTEM STATUS Display –** The LCD display is used to display User instructions and Error and Operational Codes with messages. The system includes a 2 x 20 character alpha-numeric display. The viewing area of this display is approximately 0.73 inches high by 3.27 inches wide and has green characters on a black background.

5.4.3 Energy Generator Indicators

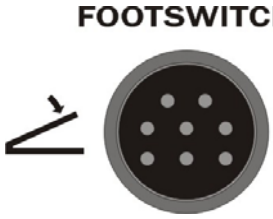
There are 4 colored LED's to indicate the display and operational status of the Energy Generator.

Graphic	Description
	**SET Indicator –** A green LED will be illuminated when the values displayed on the Front Panel are the set values.
	**ARMED Indicator –** A yellow LED will be illuminated when the system is in the CATHETER CONNECTED Mode.
	**COMPLETED Indicator –** A green LED will be illuminated when the system has finished its energy delivery.
	**FAULT Indicator –** A red LED will be illuminated when the system has encountered a fault.

5.4.4 Energy Generator Front Panel Receptacles and Connections

Graphic	Description
	**RF OUTPUT CABLE Connection –** Provides the means for delivering radiofrequency energy to the Ablation Catheter and a means for determining the size/type of catheter connected. Next to this electrical connector is the pneumatic connector for use with the HALO^{360+} Ablation Catheter and Sizing Balloon.

5.4.5 **Energy Generator Rear Panel Functions**

Graphic	Description
	**Equipotential Ground Stud –** Provides a means of securely linking the earth grounds of the Energy Generator to other grounded equipment.
	**FOOTSWITCH Receptacle –** This receptacle accepts the electrical connector leading to the Footswitch.
	**Power Access Module –** This module contains both the ON/OFF switch and the fuses. The voltage is selected by the orientation of the fuse drawer as marked.
	**Volume Control –** For adjusting the sound output volume.
	**USB Port –** For manufacturing and testing purposes by BÂRRX Medical, Inc. personnel only.

6 ENERGY GENERATOR AND ACCESSORIES

6.1 Introduction

The HALO^{FLEX} Energy Generator, Models 1190A-115A & 1190A-230A, delivers radiofrequency energy at 460 kHz in a bipolar mode to the Ablation Catheter. The Energy Generator includes an inflation system for Balloon Based Catheters. The Energy Generator measures and displays treatment power, energy density, balloon size and balloon pressure.

6.2 Accessories

Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1. When ancillary equipment is connected to the signal input part or signal output part of the HALO^{FLEX} Energy Generator, it is recommended to connect such equipment to the power outlet through a separation transformer and therefore to comply with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical services department or your local representative.

6.2.1 HALO^{FLEX} Footswitch

The Footswitch allows the operator to initiate or cease the delivery of RF energy and balloon inflation and deflation without using his or her hands. This is a non-sterile device, connected to the energy generator with a 3-meter cable.

The Footswitch has two operational controls (Foot Pedals) which will duplicate the functions of the RF POWER CONTROL ON/OFF Button and the AUTOMATIC INFLATE Up and DEFLATE Down Buttons.

The Footswitch Unit houses two Foot Pedals, the basic operation of each Foot Pedal is: press once and release to engage, and press once and release to disengage.

6.2.1.1 One Foot Pedal is labeled “AUTO INFLATION” and functions as a toggle switch that alternatively operates as the Auto Inflation Up and Auto Inflation Down Buttons. The color of this Foot Pedal is gray.

- A single depression of this Foot Pedal will automatically inflate the balloon to the preset inflation pressure depending on catheter type.
  - If a Sizing Balloon is connected, the Energy Generator will inflate the balloon to the Sizing Balloon inflation pressure.
  - If a Balloon Based Ablation Catheter is connected, the Energy Generator will inflate the balloon to the Ablation Catheter inflation pressure.
  - If a Non-Balloon Based Ablation is connected, this Foot Pedal function will be disabled.
- A successive depression of this Foot Pedal will automatically deflate the balloon to a minimum of -0.136 atm (-2.0 psi).

6.2.1.2 The other Foot Pedal is labeled "RF POWER ON/OFF" and initiates delivery of RF energy in the same manner as the RF POWER CONTROL ON/OFF Button on the Energy Generator Front Panel. The color of this Foot Pedal is blue.

- If RF energy delivery has been enabled by inflating the balloon to the pressure required to enable RF delivery, a single depression of the RF POWER ON/OFF Foot Pedal initiates delivery of RF energy. RF energy is continued regardless of the state of the Foot Pedal (i.e. whether the user maintains the Foot Pedal depressed, or releases the Foot Pedal).
- If RF energy is active and the user releases the Foot Pedal, and then depresses the foot pedal a second time, RF energy delivery ceases. **CAUTION: Do not continually hold down or repeatedly depress RF POWER ON/OFF Foot Pedal during the procedure.**

6.2.1.3 Footswitch Cleaning Instructions: Use a mild detergent and damp cloth, followed by a disinfectant to clean the Footswitch. The Footswitch is not sterilizable.

6.2.1.4 Disconnect Footswitch after use. Do not wrap Footswitch Cable excessively tight around Footswitch.

6.2.2 HALO^{FLEX} Output Cable

The Output Cable is a reusable cable that connects the Sizing Balloon and the Ablation Catheters to the Energy Generator. The Output Cable contains both the electrical and pneumatic conductors required to interface the Sizing Balloon and Ablation Catheters to the HALO^{FLEX} Energy Generator. It allows the Energy Generator to control inflation and deflation of Balloon Based Ablation Catheters and Sizing Balloons. The Output Cable is also the source for delivering power to Ablation Catheters.

The Output Cable is approximately 9' in length and 3/4" in diameter.

The Output Cable terminates into a 10 pin electrical connector (4 for RF and 5-6 for electrical signals) at both ends, and a male luer pneumatic fitting on the catheter end and a female luer pneumatic fitting at the generator end. The Output Cable incorporates a "clamp" that allows it to be fixed to a patient's bed sheets to support the weight of approximately 3' of the Output Cable. The position of the clamp is adjustable along the segment of the Output Cable that is from 6" to 18" from the catheter end of the Output Cable.

Disconnect Output Cable after use.

6.2.3 Disposable Devices

The HALO^{FLEX} Energy Generator is compatible with the following disposable devices:

Disposable Type	Model #	Description
Balloon Based Ablation Catheters	32041-18	18 mm HALO^{360+} Ablation Catheter
	32041-22	22 mm HALO^{360+} Ablation Catheter
	32041-25	25 mm HALO^{360+} Ablation Catheter
	32041-28	28 mm HALO^{360+} Ablation Catheter
	32041-31	31 mm HALO^{360+} Ablation Catheter
Non Balloon Based Ablation Catheters	90-9100	HALO^{90} Ablation Catheter
Sizing Balloons	3441-B	HALO^{360} Sizing Balloon
	3441-C	HALO^{360+} Sizing Balloon

For procedural usage steps and a description for each device, see the Instructions for Use provided with the disposable device.

7 SET-UP PROCEDURE AND INSTRUCTIONS FOR USE

7.1 Connection of Accessories

7.1.1 Output Cable Connections

Connect the provided Output Cable to the Energy Generator by attaching the large, electrical connector on the Output Cable to the mating connector on the front panel of the Energy Generator. Place the white alignment dot on the large electrical connector at 12 o'clock position for proper pin alignment. Once the pins have been mated correctly, tighten the threaded exterior connector ring to secure the Output Cable to the Energy Generator.

Connect the pneumatic line adjacent to the large, electrical connector on the Output Cable to the male luer connection on the front panel of the Energy Generator. Press the Output Cable bayonet style connector firmly against the Energy Generator connection until the connectors snap together.

7.1.2 Footswitch Connection (optional)

Connect the provided Footswitch by inserting its electrical connector into the socket directly under the label "FOOTSWITCH" on the rear panel of the Energy Generator. Place the white alignment dot on the footswitch connector at 12 o'clock position for proper pin alignment. Once the pins have been mated correctly, tighten the threaded exterior connector ring to secure the Footswitch to the Energy Generator.

7.1.3 Catheter Connections

The Sizing Balloon and Ablation Catheter pneumatic and electrical connectors are connected to the Energy Generator using the Output Cable that is supplied with the Energy Generator. Prior to connecting the Output Cable pneumatic line connector to any Sizing Balloon or Balloon Based Ablation Catheter, it is necessary to place the supplied hydrophobic filter between the pneumatic connector located at the proximal end of the Sizing Balloon or Ablation Catheter and the pneumatic connector on the distal end of the Output Cable. This filter is to ensure fluids are not aspirated into the Output Cable in the event of a catheter leak. Failure to attach the filter may result in the fluid contamination of the Output Cable and mandatory Output Cable replacement.

Attach the catheter connection only when the Energy Generator is powered OFF or is in the STANDBY Mode.

7.2 Power-Up

Plug the Energy Generator into a grounded hospital grade power outlet (extension cords and/or adapter plugs must not be used). Connect the Output Cable to the Energy Generator. Turn the power on using the ON/OFF switch, which is located on the power access module on the rear panel.

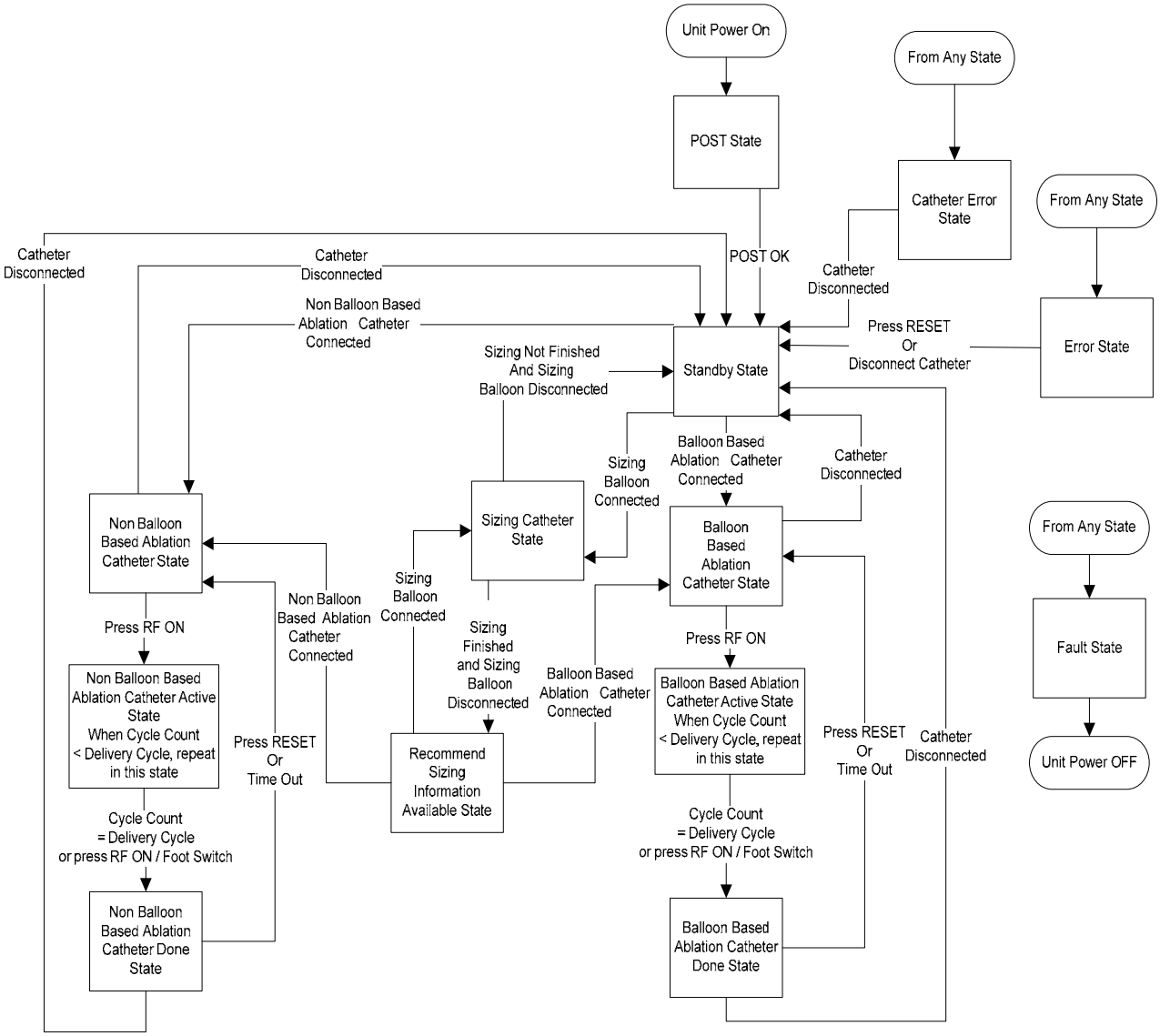
The Energy Generator will perform a self-test during which a tone will sound, digital displays will show 'Self Test In Progress' and all indicators will be ON. Check that all digit segments and indicators illuminate, and that a tone is audible. If any of the segments or indicators fails to light, or if no tone is heard, DO NOT USE the system. Contact BÂRRX Medical, Inc.

In twenty to twenty-five seconds, the self-test will be completed, and the Energy Generator will enter the STANDBY Mode with the digital displays registering the default set values. No procedure settings can be entered during the STANDBY Mode. If the Energy Generator goes directly into a FAULT Mode upon start-up, DO NOT USE the system, and contact BÂRRX Medical, Inc.

7.3 Energy Generator Modes

The Energy Generator operates in one of seven modes, POST (Power ON Self Test), STANDBY, CATHETER CONNECTED, ACTIVE (RF ON), ABLATION COMPLETE, ERROR, and FAULT. Refer to Figure 2.

Figure 2 - State Diagram of HALO^{FLEX} Energy Generator Modes



7.3.1 POST (Self-Test) Mode

The POST is performed when AC mains power is turned on. The following tests are performed:

- A test of the CPU and RAM
- A test of the CPU and ROM
- A test of the CPU Configuration
- A test of the CRC of the program contents
- A test of the watchdog shutdown hardware
- A test of the power
- A test of the impedance
- A test of the voltage
- A test of the current
- A test of the reference voltage
- A test of the real time clock
- A test of the inflation subsystem's pressure sensors for zero offset and transducer calibration
- A test of the air pump operation
- A test of the displays and indicators (must be confirmed by an observer)
- A test of the audible indicator (must be confirmed by an observer)
- A test for switch and foot switch pressed
- The RF Generator's software version number is displayed on the LCD panel for a minimum period of 2 seconds

System Transitions

- If all self-tests pass, the system transitions to the STANDBY Mode.
- If self-test fails, the result is monitored by the system, the system will automatically transition to the FAULT Mode. In the FAULT Mode, the LCD will display instructions to the User to resolve the FAULT condition. Since the system does not monitor display indicators nor the audible indicator, failures of these features during self-test will not result in a transition to the FAULT Mode.

7.3.2 STANDBY Mode

7.3.2.1 The Standby Mode is automatically entered following a successful POST and displays "Ready Connect Catheter" on the LED Display.

7.3.2.2 None of the User controls are accessible when the system is in the Standby Mode.

7.3.2.3 The system will remain in the Standby Mode until a catheter is connected, then will enter the CATHETER CONNECTED Mode.

7.3.3 CATHETER CONNECTED Mode

7.3.3.1 The CATHETER CONNECTED Mode is automatically entered following the connection of either an Ablation Catheter or a Sizing Balloon.

7.3.3.2 When a catheter is connected to the Energy Generator, it will recognize the Sizing Balloon or the type of Ablation Catheter connected and allows activation of system features, accordingly. The procedure settings can be entered during the CATHETER CONNECTED Mode.

7.3.3.3 The displays and functions of the CATHETER CONNECTED Mode depend on the type of catheter connected, i.e. an Ablation Catheter or a Sizing Balloon, as defined below:

Ablation Catheter Connected

- The Ablation CATHETER CONNECTED Mode is automatically entered after successful completion of a POST and following connection of an Ablation Catheter, or after exiting the Ablation Complete Mode.

- An LED display indicating the system is in the Ablation CATHETER CONNECTED Mode and the energy density parameter can be adjusted (illumination of the SET LED).

- In the Ablation CATHETER CONNECTED Mode, the user will be able to change the value of energy density.

- See appropriate Ablation Catheter Instructions for Use, included with the catheter, for procedural usage steps once in CATHETER CONNECTED Mode.

Sizing Balloon Connected

- The Sizing Balloon Connected Mode is automatically entered following successful completion of a POST and connection of a Sizing Balloon, or after exiting the Calibration Complete or Sizing Complete Modes.

- In the Sizing Balloon Connected Mode, the user will not be able to change any parameters.

- See appropriate Sizing Balloon Instructions for Use, included with the catheter, for calibration and procedural usage steps once in CATHETER CONNECTED Mode.

Inflation Capability

- In the CATHETER CONNECTED Mode, the INFLATE and DEFLATE capability is enabled if you have connected either a Sizing Balloon or a Balloon Based Ablation Catheter by pressing

either the AUTOMATIC INFLATE Up or DEFLATE Down Buttons or the AUTO INFLATION Foot Pedal on the Footswitch. Note the AUTOMATIC INFLATE Up or DEFLATE Down Buttons and Foot Pedal work as a toggle switch in that a single depression will inflate the balloon to the desired pressure and a subsequent depression will deflate the balloon. Inflation pressure specifications are gauge pressures.

- While using the INFLATE and DEFLATE capability, an LED display on the Front Panel is indicating the pressure of the inflation system.
- The INFLATE capability will inflate the balloon to a predetermined pressure based on the type of catheter connected, i.e. either a Sizing Balloon or Ablation Catheter.
- The DEFLATE capability will deflate the balloon to a predetermined pressure.
- The Energy Generator has the ability to measure the mass flow rate of the air inflating a Sizing Balloon. The mass flow rate is available to the ENERGY GENERATOR CPU. This allows for calculation of balloon diameter for sizing inner diameter of esophagus.
- An audible indicator will confirm when the system is pressurized beyond 0.02 atm (0.30 psi). The audible indicator will provide a periodic audible tone that is distinguishable from the RF ON tone, while the balloon is inflated. The tone will increase in frequency indicating the inflation pressure has been achieved.
- While using the INFLATION capability:
  - If the two pressure transducers differ by more than 0.5 psi the system will enter the FAULT Mode:
    - A brief non-recoverable error tone is generated, and then the tone is turned off.
    - The LCD displays an error message indicating ‘H23’ error code.
    - The system will remain in the INFLATION FAULT State until AC mains power is cycled.
  - If the system does not achieve the set pressure within a specified time allowed for each catheter, the system will enter the ERROR Mode:
    - A brief recoverable error tone is generated, and then the tone is turned off.
    - The LCD displays an error message.
    - Depending on the type of recoverable error, the system will remain in the ERROR Mode until the RESET button is pressed or for 3 seconds.

7.3.4 SIZING CATHETER State (Sizing Balloons Only)

- The SIZING CATHETER State is part of CATHETER CONNECTED Mode when a Sizing Balloon is connected.
- The Sizing Balloon must be calibrated prior to sizing. Calibration is initiated when the CALIRATION button is depressed. See Sizing Balloon Instructions for Use, provided with the catheter, for calibration steps. The calibration function will normalize an un-calibrated (new) balloon to 33.7 mm and will display that value on the LED after performing the calibration function
- Upon completion of successful calibration, the Sizing Balloon will be ready for sizing.
- A sizing measurement will be obtained when the INFLATE Button or the INFLATE/DEFLATE Footswitch pedal is pressed. The Energy Generator will automatically inflate and deflate the balloon.
- The Energy Generator will calculate the diameter of the Sizing Balloon while inflated and display this diameter on the balloon diameter LED display.
- The Energy Generator will display the "recommended" Ablation Catheter diameter in the LCD display per the following table.

Automatic Sizing Estimate (mm)	Recommended Balloon Electrode Size (mm)
<18.0	Narrowed Esophagus Balloon Ablation Not Recommended
18.0-21.9	18
22.0-24.9	22
25.0-27.9	25
28.0-30.9	28
31.0 – 36.9	31
≥37	Sizing Balloon Unconstrained Repeat Sizing Check Position

- At Sizing Balloon catheter disconnection, the Energy Generator will display the smallest diameter measured and provide a final Ablation Catheter recommendation based on all sizing measurements.

System Transitions

- The System will deflate the balloon if the DEFLATE Button or the INFLATE/DEFLATE Foot Pedal is pressed during inflation.
- The System transitions to the ERROR Mode if a recoverable error is detected.

- The System transitions to the FAULT Mode if a non-recoverable error is detected.

Warning: If an ERROR or FAULT is detected for a Sizing Balloon, it may be necessary to manually deflate the Sizing Balloon by depressing the Down AUTOMATIC DEFLATE Button (down arrow next to the balloon pressure display) or by connecting a syringe to the pneumatic connector and aspirate the air from the Sizing Balloon. Under endoscopic visualization verify that the Sizing Balloon is completely deflated before removing the balloon.

7.3.5 TEST Function Mode (Ablation Catheters Only)

The TEST Function is entered from the CATHETER CONNECTED Mode when the RF POWER CONTROL ON/OFF Button or the RF POWER ON/OFF Foot Pedal is pressed, an Ablation Catheter is connected and, for Balloon Based Ablation Catheters, the pressure in the balloon is at or above the minimum RF delivery pressure.

- The RF ON indicator (RF POWER CONTROL ON/OFF Button) illuminates briefly and a short tone sounds to indicate the delivery of RF energy.
- The system sequentially delivers 10W of power to each selected electrode and tests to ensure there are no shorts or open circuits.

System Transitions

- The System transitions to the ACTIVE Mode, after successfully completing the TEST Function. The system will then deliver the desired RF energy density through each electrode.
- Depression of the RF ON/OFF button or foot pedal a second time will cease the RF test delivery. They system will transition back to CATHETER CONNECTED Mode. For Balloon Based Ablation Catheters, the Energy Generator will deflate the balloon to a minimum of -2.0 psi.
- The System transitions to the ERROR Mode if a recoverable error is detected.
- The System transitions to the FAULT Mode if a non-recoverable error is detected.

7.3.6 ACTIVE (RF ON) Mode (Ablation Catheters Only)

The RF ON Mode is entered from the TEST Function Mode when an Ablation Catheter has successfully passed the RF Test.

- The RF ON indicator is lit (illumination of the RF POWER CONTROL ON/OFF Button).
- A tone is generated.
- The System sequentially delivers energy to each electrode using the power delivery algorithm to maintain the set power to each electrode.
- The System will deliver RF energy to the electrode until the selected energy density has been delivered or the energy delivery cycle has been halted by user intervention (i.e. pressing the ON/OFF POWER CONTROL Button or

releasing and pressing the RF POWER ON/OFF Foot Pedal) or by detection of an Error or a Fault.

System Transitions

- The System will transition to the DONE Mode if the RF POWER ON/OFF Foot Pedal is released and depressed a second time. For a Balloon Based Ablation Catheter, subsequent to RF energy delivery, the Ablation Catheter will automatically deflate.
- The System will transition to the DONE Mode if the RF POWER CONTROL ON/OFF Button is pressed. For a Balloon Based Ablation Catheter, subsequent to RF energy delivery, the Ablation Catheter will automatically deflate.
- The System will transition to the DONE Mode if the set energy density has been reached. For a Balloon Based Ablation Catheter, subsequent to RF energy delivery, the Ablation Catheter will automatically deflate.
- The System will transition to the ERROR Mode if a recoverable error is detected.
- The System will transition to the FAULT Mode if a non-recoverable error is detected.

Warning: If an ERROR or FAULT is detected for a Balloon Based Ablation Catheter, it may be necessary to manually deflate the Ablation Catheter by depressing the Down AUTOMATIC DEFLATE Button (down arrow next to the balloon pressure display) or by connecting a syringe to the pneumatic connector and aspirate the air from Ablation Catheter. Under endoscopic visualization verify that the Ablation Catheter is completely deflated and observe the treatment effect.

7.3.7 Shutdown Conditions

During RF delivery, the following conditions will cause the software to cease RF output and transition directly into ABLATION COMPLETE mode:

- The energy limit set by the operator is reached.
- The energy delivery duration reaches its maximum time on.
- The RF POWER ON/OFF Foot Pedal is released and then depressed a second time.
- The RF POWER CONTROL ON/OFF Button is depressed once.
- An open circuit has been detected (i.e. the measured impedance is too high).
- A short circuit has been detected (i.e. the measured resistance is too low).
- The measured power exceeds the power limit set by the user.
- The measured power is less than the Power Compliance percentage.
- The measured voltage is too high.
- The measured current is too high.
- Any FAULT.
- Any ERROR.

7.3.8 ABLATION COMPLETE Mode (Ablation Catheters Only)

- The RF ON indicator is not lit.

System Transitions

- The System will transition to the CATHETER CONNECTED Mode after successful RF delivery and after balloon deflation for Balloon Based Ablation Catheter, after 1 second for Non Balloon Based Ablation Catheters, or if the Reset Button is pressed.
- The System will transition to the ERROR Mode if a recoverable error is detected.
- The System will transition to the FAULT Mode if a non-recoverable error is detected.

7.3.9 ERROR/OPERATIONAL CODE Mode

- The RF ON indicator is not lit.
- A brief recoverable error tone is generated, and then the tone is off.
- The LCD displays an Operational Code and message with brief instructions for resolving the error.

Warning: Complete balloon deflation must be visually verified through the endoscope prior to repositioning or attempting to remove a Balloon Based Ablation Catheter or Sizing Balloon.

System Transitions

- The System will remain in the ERROR Mode until RESET Button is pressed or for 3 seconds depending on the specific error, at which time the system will transition to the CATHETER CONNECTED Mode if a catheter is connected and STANDBY Mode if no catheter is connected.

7.3.10 FAULT Mode

- The RF ON indicator is not lit.
- A brief non-recoverable error tone is generated, and then the tone is off.
- The FAULT LED is illuminated.
- The LCD displays an Operational Code, and message with brief instructions for resolving the error.

Warning: Complete balloon deflation must be visually verified through the endoscope prior to repositioning or attempting to remove a Balloon Based Ablation Catheter or Sizing Balloon**.**

System Transitions

- The System will remain in the FAULT Mode until AC mains power is cycled.

8 TROUBLESHOOTING

8.1 Problem: No RF Power Output

- Energy Generator not plugged in.
- Energy Generator not turned on.
- Energy Generator in STANDBY Mode.
- Energy Generator in FAULT Mode.
- Energy Generator still in ABLATION COMPLETE Mode.
- Fault in accessory or Footswitch.
- OUTPUT CABLE not connected to Energy Generator.
- No Ablation Catheter connected.
- Defective Ablation Catheter.
- ENERGY DENSITY parameter not set.
- Internal Energy Generator failure.
- Balloon Inflation Error. The pressure in the Balloon Based Ablation Catheter is less than the target pressure.

8.2 Operational and Fault Codes

If a fault condition occurs, the System Status display on the Front Panel will display an Operational Code, and all others will be blank. The interpretation of the Operational, Error and Fault Codes, as well as possible causes and solutions are listed in Tables 3.A, 3.B, 3.C and 3.D.

In the event of an Operational /Error or Fault Code, endoscopic visualization must always be used to verify complete balloon deflation if using a Balloon Based Ablation Catheter or Sizing Balloon.

If the Energy Generator displays an E95 Operational Code when using a Balloon Based Ablation Catheter or Sizing Balloon, this is probably due to an air leak within the system. In such situations verify the following connections are secure:

- The pneumatic connector between the Energy Generator and the Output Cable;
- The pneumatic connector between the Output Cable and the HALO Filter;
- The connection between the HALO Filter and the Ablation Catheter.

If the E95 Operational Code is observed again, there may be an air leak in the Ablation Catheter. Under endoscopic visualization, confirm that the balloon is fully deflated and then remove the Ablation Catheter. If the balloon is not deflated by depressing the deflate control button or by depressing the Auto Inflation Foot Pedal then manually deflate the balloon using a syringe via the pneumatic connector, then remove and replace the Ablation Catheter.

Table 3.A. Post Faults (Unrecoverable)

Error Code	Description	System Status Messages	Auto Deflate function active on Error for Balloon Based Catheters
P01	**POST CPU Configuration Operational Code**	Disconnect Catheter P01- Cycle Power	**N/A**
P02	**POST ROM Test Operational Code**	Disconnect Catheter P02- Cycle Power	**N/A**
P03	**POST RAM Test Operational Code**	Disconnect Catheter P03- Cycle Power	**N/A**
P04	**POST Power Operational Code**	Disconnect Catheter P04- Cycle Power	**N/A**
P05	**POST Impedance Operational Code**	Disconnect Catheter P05- Cycle Power	**N/A**
P06	**POST Voltage Operational Code**	Disconnect Catheter P06- Cycle Power	**N/A**
P07	**POST Current Operational Code**	Disconnect Catheter P07- Cycle Power	**N/A**
P08	**POST Reference Voltage Operational Code**	Disconnect Catheter P08- Cycle Power	**N/A**
P09	**POST Watchdog Test Operational Code**	Disconnect Catheter P09- Cycle Power	**N/A**
P10	**POST Output Transformer Impedance Operational Code**	Disconnect Catheter P10- Cycle Power	**N/A**
P11	**POST Pressure Sensor Offset Operational Code**	Disconnect Catheter P11- Cycle Power	**N/A**
P12	**POST Pressure Reference Voltage Operational Code**	Disconnect Catheter P12- Cycle Power	**N/A**
P15	**POST Real Time Clock Test Operational Code**	Disconnect Catheter P15- Cycle Power	**N/A**
P16	**POST Real Time Clock Date Operational Code**	Disconnect Catheter P16-Cycle Power	**N/A**
P17	**POST Switch Closed Operational Code**	Disconnect Catheter P17- Cycle Power	**N/A**

Table 3.B. Software/Hardware Faults (Unrecoverable)

Error Code	Description	System Status Messages	Auto Deflate function active on Error for Balloon Based Catheters
H10	**COP Operational Code**	Disconnect Catheter H10- Cycle Power	**Yes**
H11	**Illegal CPU Instruction**	Disconnect Catheter H11- Cycle Power	**Yes**
H12	**Duplicate Variable Operational Code**	Disconnect Catheter H12- Cycle Power	**Yes**
H13	**Software Operational Code**	Disconnect Catheter H13- Cycle Power	**Yes**
H15	**Reference Voltage Operational Code**	Disconnect Catheter H15- Cycle Power	**Yes**
H16	**V_{rms} Offset Operational Code**	Disconnect Catheter H16- Cycle Power	**Yes**
H17	**I_{rms} Offset Operational Code**	Disconnect Catheter H17- Cycle Power	**Yes**
H18	**P_{meas} Offset Operational Code**	Disconnect Catheter H18- Cycle Power	**Yes**
H19	**RF ON Synch Operational Code**	Disconnect Catheter H19- Cycle Power	**Yes**
H20	**Pressure Out of Range Operational Code**	Disconnect Catheter H20- Cycle Power	**Yes**
H22	**Output Transformer Channel Set Operational Code**	Disconnect Catheter H22- Cycle Power	**Yes**
H23	**Duplicate Pressure Operational Code**	Disconnect Catheter H23- Cycle Power	**Yes**

TABLE 3.C. Catheter Errors (Recoverable)

Error Code	Description	System Status Messages	Auto Deflate function active for Balloon Based Catheters
C50	**EEPROM CRC Code**	C50- Reconnect or Discard Catheter	**No**
C51	**Invalid Catheter ID Code**	C51- Reconnect or Discard Catheter	**No**
C52	**Expired Catheter Code**	C52- Max Time Reached Discard Catheter	**Yes**
C53	**Catheter Use Exceeded Code**	**Sizing Balloon:** Discard Catheter C53-Max Use Reached _____ *nn*mm Recommended **Balloon Based Ablation Catheter:** Discard Catheter C53-Max Use Reached _____ nnn% nnn% nnn% Energy Delivered **Non-Balloon Based Ablation Catheter:** Discard Catheter C53-Max Use Reached _____ nn% Energy Delivered	**Yes**
C55	**Catheter Type Code**	C55- Reconnect or Discard Catheter	**Yes**
C56	**Filter Blocked Code**	C56-Filter Blocked Remove Filter _____ Deflate with Syringe Discard Catheter	**No**
C57	**EEPROM Setting Code**	Unusable Catheter C57-Discard Catheter	**No**

Table 3.D. — Application Operational Codes (Recoverable)

Error Code	Description	System Status Messages	Auto Deflate function active For Balloon Based Catheters	Require Reset Button
E81	**Low Impedance Error**	**Balloon Based Ablation Catheter:** E81- Catheter Too Big Check Sizing Results _____ Consider Smaller Ablation Catheter _____ nnn% nnn% nnn% Energy Delivered **Non-Balloon Based Ablation Catheter:** E81- Clean Electrode _____ nn% Energy Delivered _____ n Ablations	**Yes**	**No**
E82	**High Impedance Error**	**Balloon Based Ablation Catheter:** E82-Clean Electrode Or Poor Elec Contact _____ nnn% nnn% nnn% Energy Delivered **Non-Balloon Based Ablation Catheter:** E82-Clean Electrode Or Poor Elec Contact _____ nn% Energy Delivered _____ n Ablations	**Yes**	**No**
E83	**Voltage Limit Error**	**Balloon Based Ablation Catheter:** E83-Clean Electrode Or Poor Elec Contact _____ nnn% nnn% nnn% Energy Delivered **Non-Balloon Based Ablation Catheter:** E83-Clean Electrode Or Poor Elec Contact _____ nn% Energy Delivered _____ n Ablations	**Yes**	**No**

Error Code	Description	System Status Messages	Auto Deflate function active For Balloon Based Catheters	Require Reset Button
E84	**Current Limit Error**	**Balloon Based Ablation Catheter:** E84-Clean Electrode _____ nnn% nnn% nnn% Energy Delivered **Non-Balloon Based Ablation Catheter:** E84-Clean Electrode _____ nn% Energy Delivered _____ n Ablations	**Yes**	**No**
E85	**Duplicate Current Error**	**Balloon Based Ablation Catheter:** E85-Clean Electrode Or Poor Elec Contact _____ nnn% nnn% nnn% Energy Delivered **Non-Balloon Based Ablation Catheter:** E85-Clean Electrode Or Poor Elec Contact _____ nn% Energy Delivered _____ n Ablations	**Yes**	**No**
E86	**High Power Error**	**Balloon Based Ablation Catheter:** E86-Clean Electrode Or Poor Elec Contact _____ nnn% nnn% nnn% Energy Delivered **Non-Balloon Based Ablation Catheter:** E86-Clean Electrode Or Poor Elec Contact _____ nn% Energy Delivered _____ n Ablations	**Yes**	**No**

Error Code	Description	System Status Messages	Auto Deflate function active For Balloon Based Catheters	Require Reset Button
E87	**Power Limit Error**	**Balloon Based Ablation Catheter:** #87-Clean Electrode Or Poor Elec Contact _____ nnn% nnn% nnn% Energy Delivered **Non-Balloon Based Ablation Catheter:** #87-Clean Electrode Or Poor Elec Contact _____ nn% Energy Delivered _____ n Ablations	**Yes**	**No**
E89	**Power Compliance Error**	**Balloon Based Ablation Catheter:** #89-Clean Electrode Or Poor Elec Contact _____ nnn% nnn% nnn% Energy Delivered **Non-Balloon Based Ablation Catheter:** #89-Clean Electrode Or Poor Elec Contact _____ nn% Energy Delivered _____ n Ablations	**Yes**	**No**
E90	**AC Power Measurement Error**	**Balloon Based Ablation Catheter:** #90-Clean Electrode Or Poor Elec Contact _____ nnn% nnn% nnn% Energy Delivered **Non-Balloon Based Ablation Catheter:** #90-Clean Electrode Or Poor Elec Contact _____ nn% Energy Delivered _____ n Ablations	**Yes**	**No**

Error Code	Description	System Status Messages	Auto Deflate function active For Balloon Based Catheters	Require Reset Button
E91	**DC Power Measurement Error**	**Balloon Based Ablation Catheter:** #91-Clean Electrode Or Poor Elec Contact _____ nnn% nnn% nnn% Energy Delivered **Non-Balloon Based Ablation Catheter:** #91-Clean Electrode Or Poor Elec Contact _____ nn% Energy Delivered _____ n Ablations	**Yes**	**No**
E92	**RF Test Low Impedance Error**	**Balloon Based Ablation Catheter:** E92-Catheter Too Big Check Sizing Results ____ Consider Smaller Ablation Catheter _____ Press RESET **Non-Balloon Based Ablation Catheter:** E92-Clean Electrode Press RESET	**Yes**	**Yes**
E93	**RF Test High Impedance Error**	E93- Check Catheter Connections _____ Press RESET	**Yes**	**Yes**
E94	**RF is On Too Long**	E94-Press RESET	**Yes**	**Yes**
E95	**Pressure Leak Detected**	E95- Press RESET Air Leak _____ Inspect Connection Inspect Balloon	**Yes**	**Yes**
E96	**Balloon is not deflated**	E96- Press RESET Check Balloon	**No**	**Yes**

Error Code	Description	System Status Messages	Auto Deflate function active For Balloon Based Catheters	Require Reset Button
E97	**Balloon Movement Detected**	**Sizing Measurement ≥18 mm and < 37 mm:** 97-Balloon Migration Narrowed Esophagus _____ Or Air Leak Inspect Balloon _____ Nnmm Recommended **Sizing Measurement <18 mm:** 97-Balloon Migration Narrowed Esophagus _____ Or Air Leak Inspect Balloon _____ Balloon Ablation Not Recommended **Sizing Measurement ≥ 37 mm:** 97-Balloon Migration Narrowed Esophagus _____ Or Air Leak Inspect Balloon _____ Sizing Balloon Unconstrained	**Yes**	**No**
E98	**Catheter Calibrate Error**	E98- Press RESET Repeat Calibration	**Yes**	**Yes**

9 TECHNICAL SPECIFICATIONS

9.1 RF Output

- RF energy: **460.8 kHz ± 5%, Quasi-sinusoidal**
- Energy density: **1.0-20.0 J/cm^2**
- Maximum power: **300 W**
- Maximum voltage: **40 V_{rms}**
- Maximum current: **24 A_{rms}**
- Duty Cycle: **Max 1.5 seconds ON, MIN 1 seconds OFF**

9.2 Setting Limits

- Power for HALO^{90} Ablation Catheter: **104 W (1.0 Ω)**
- Power for HALO^{360+} Ablation Catheter: **300 W (2.0 Ω)**
- Energy density: **10.0 -15.0 J/cm^2**
- Generator diameter measurement capability: **12.5 mm to 34 mm ± 1.5 mm**
- Inflation pressure limits: **LO to 0.31 atm**

9.3 Shutdown Limits

During RF delivery, the following conditions will cause the software to cease RF output and transition directly into ABLATION COMPLETE Mode.

- The RF POWER ON/OFF Foot Pedal: **Is released and depressed a second time**
- The RF POWER CONTROL ON/OFF Button: **Is released and depressed a second time**
- Measured Impedance (Z): **0.4 Ω ≤ Z ≤ 7 Ω for HALO^{360+}**
  0.5 Ω ≤ Z ≤ 30 Ω for HALO^{90}
- Measured Voltage (V): **>37 Volts for longer than 100 ms**
- Any FAULT
- Any ERROR/Operational Code

9.4 Measurement Accuracy

- Power: **±15%, ±3 W** over the resistance load range of **0.5 Ω to 20 Ω** for power levels **above 30 W**

9.5 Mechanical Specifications

- Size (**Energy Generator)**: **16" wide x 21" deep x 6 1/8" high. (39.4 cm** x **51.6 cm** x **15.9 cm).**
- Weight (**Energy Generator**): **31 lb (14 kg)**
- Moisture protection rating: **IPX0**

9.6 Electrical Safety

- Class 1, Type "BF" applied part
- Ordinary Equipment RF Energy Generator

9.7 Environmental Specifications

- Operational temperature: **20°C to 30°C**
- Humidity functional: **20% to 65%** non-condensing
- Storage temperature: **-40°C to 70°C**
- Humidity storage: **20% to 85%** non-condensing
- Altitude up to **7000 feet (2,134 meters) above sea level**

9.8 Fuses and Line Voltage Ranges

- Line Voltages: **110 – 120 VAC/ 60Hz** and **220 – 240 VAC/50 Hz**
- Rated input current: **<6.3A, 110-120 VAC, 60Hz, or <4.0A, 220-240 VAC, 50Hz**
- Replace mains fuses as follows:
  - **Littelfuse p/n 021306.3 (6.3A) for the 110-120 VAC/60Hz System**
  - **Littelfuse p/n 218004P (4.0 A) for the 220-240 VAC/50Hz System**
- Power Output Restrictions: **Power output is available over a 0.4Ω - 30 Ω range.**

9.9 Footswitch Specifications

- Electric

9.10 Output Cable Specification

The Energy Generator system limits the voltage through the Output Cable to maximum 40 Vrms. The Output Cable insulation wall thickness is 25 mils min. The Output Cable insulation dielectric strength is rated for 7500V (300V/mil).

9.11 Ablation Catheters

- The Ablation Catheters comply with IEC60601-2-2 requirements and are voltage rated for 75 Vrms.

9.12 Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The HALO^{FLEX} System is intended for use in the electromagnetic environment specified below. The customer or the user of the HALO^{FLEX} System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment— Guidance
RF emissions CISPR11	Group 2	The HALO^{FLEX} System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR11	Class A	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

9.13 Measurement Accuracy Graphs

Figure 4 - Power Output vs. Power Setting

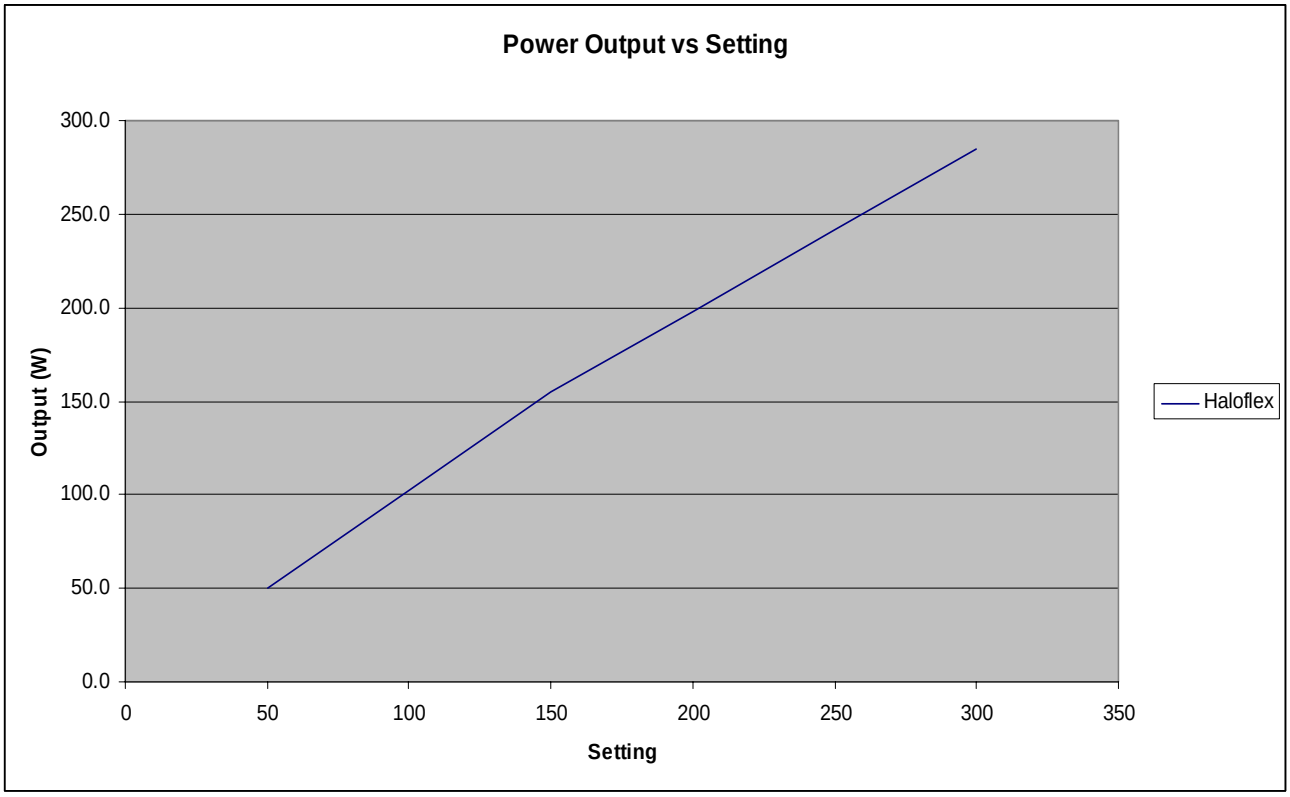


Figure 5

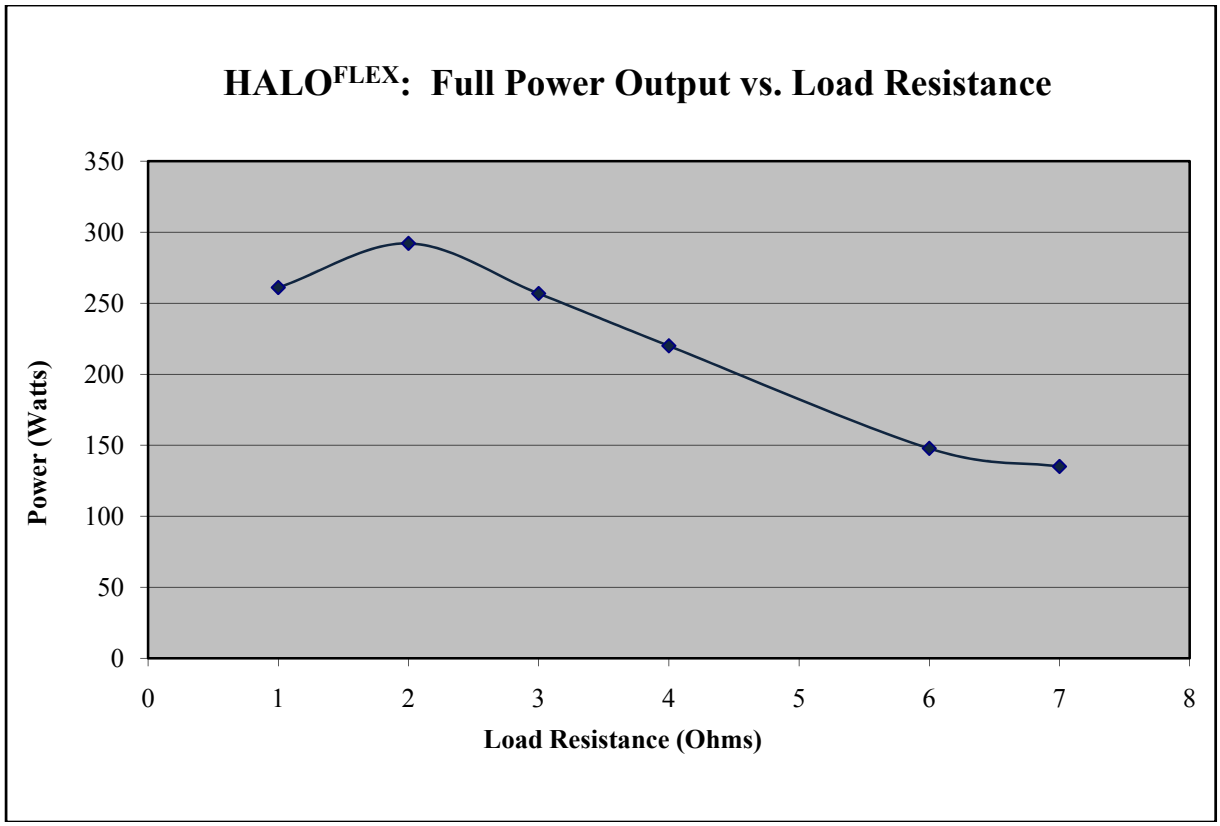
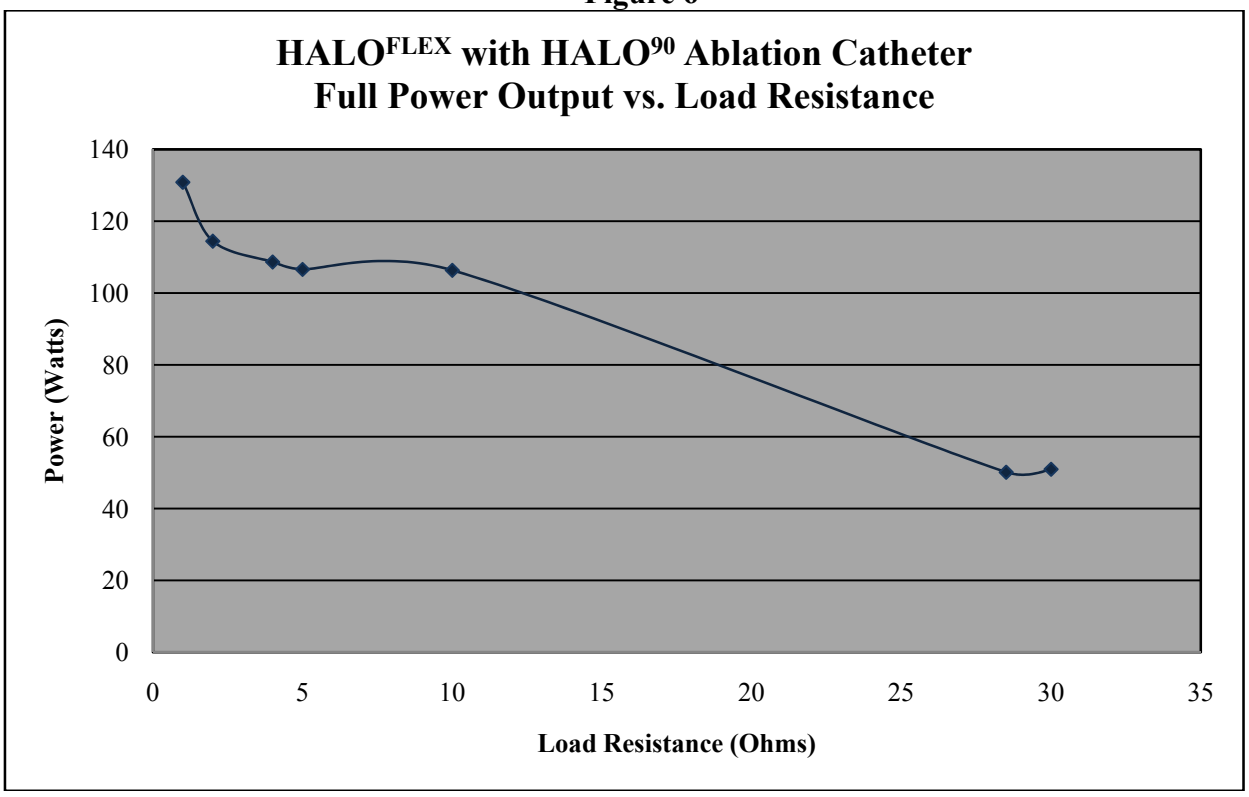
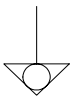


Figure 6



10 LABELING SYMBOLS AND USER INFORMATION

Alternating Current	
Attention: consult accompanying documents	
Catheter	
Dangerous Voltage	
Defibrillator-proof, Type BF Equipment	
Potential Equalization Ground	
Footswitch	
Fuses	
Non-Ionizing Radiation	
Power OFF	
Power ON	
RF POWER CONTROL OFF	
RF POWER CONTROL ON	
This product contains no detectable latex.	
Up: Increases the value displayed in the adjacent numeric LED display. A single depression of the key increases the value by one unit. Continuous depression increments the display to the maximum value.	
Down: Decreases the value displayed in the adjacent numeric LED display. A single depression of the key decreases the value by one unit. Continuous depression decreases the display to the minimum value.	
Volume Control: For adjusting the sound output volume.	
WEE Label: For end of life return and recycle information, contact BÂRRX Medical, Inc.	
USB Port: For manufacturing and testing purposes by BÂRRX Medical, Inc. personnel only.	

11 WARRANTY INFORMATION

11.1 BÂRRX Medical, Inc. warrants that, at the time of shipment, BÂRRX Medical, Inc. products (i) shall conform to their published specifications as BÂRRX Medical, Inc. may revise from time to time, and (ii) shall be free of defects in materials and workmanship, and (iii) shall be manufactured in accordance with GMP, and (iv) disposable product shall have no less than one (1) year remaining shelf life. This warranty shall apply for a single use with one patient: BÂRRX Medical, Inc. may, at its option, repair or replace any products which do not meet the preceding warranty, or refund the product purchase price.

11.2 Warranty shall not apply to products or spare parts that have been modified or altered in any manner by anyone other than BÂRRX Medical, Inc., or to defects caused (a) through no fault of BÂRRX Medical, Inc. during shipment to or from Buyer; (b) by the use or operation in an application or environment other than that intended or recommended by BÂRRX Medical, Inc.; (c) by service by anyone other than employees of, or persons approved in writing by BÂRRX Medical, Inc.; or (d) by accident, negligence, misuse, or other causes other than normal use.

11.3 Replacement products and parts supplied under this warranty shall carry only the unexpired portion of the original warranty. The applicable warranty period for all products is one (1) year from date of shipment.

11.4 The warranties set forth in this section are the exclusive warranties with respect to the products, and are given and accepted in lieu of any and all other warranties, guarantees, conditions and representations express or implied, concerning the merchantability, satisfactory quality or fitness for a particular purpose, or that the operation of the products will be uninterrupted or error free. Notwithstanding the foregoing, BÂRRX Medical, Inc does not exclude liability to the extent that such liability may not be excluded or limited by law.

11.5 In no event shall BÂRRX Medical, Inc. be liable for the cost of procurement of substitute products by the customer or for any special consequential or incidental damages. This limitation shall apply even if BÂRRX Medical, Inc. has been advised of the possibility of such damages, and notwithstanding any failure of essential purpose of any limited remedy provided herein.

11.6 Extended Warranties are available. Please contact BÂRRX Medical, Inc.

12 FORMS

BÂRRX MEDICAL	Physician Feedback Form			No.:
	Reference:QSP-0024	PCO#10009	Revision: A	Form-0021

Representative reporting complaint					
Report completed by:					
Date Report initiated:					
Date complaint occurred					
List all products involved:					
Product Description					
Model #					
Manufacturer	BÂRRX Medical Inc.	BÂRRX Medical Inc.	BÂRRX Medical Inc.	BÂRRX Medical Inc.	BÂRRX Medical Inc.
Lot or Serial number					
RGA (if applicable)					
To be returned to Manufacturer?	☐ YES ☐ NO ☐ N/A	☐ YES ☐ NO ☐ N/A	☐ YES ☐ NO ☐ N/A	☐ YES ☐ NO ☐ N/A	☐ YES ☐ NO ☐ N/A

Complainant name & Title	
Complainant Organization	
Complainant Address	
Complainant Telephone	
Complainant Fax	
Complainant Email	
Device Used in Patient	☐ YES ☐ NO IF YES, fill out sections a, b & c below
a) Status of patient before procedure	
b) Status of patient after procedure	
c) Death, Serious Injury involved	☐ YES ☐ NO If yes, complete section d
d) Was death or injury directly due to device	☐ YES ☐ NO If yes, complete section e
e) Name of physician using the device:	

Description of Complaint

Physician Name: _____

Hospital Name: _____

Address: _____

Phone #: _____ **Fax #:** _____ **E-Mail** _____

Product Information:

☐ HALO^{FLEX} System ☐ HALO^{360} System ☐ HALO$^{360/360+}$ Ablation Catheter
☐ HALO$^{360/360+}$ Sizing Balloon ☐ Accessories
☐ HALO^{90} System ☐ HALO^{90} Ablation Catheter ☐ Accessories ☐ Other_____

Experience with the system:
(What lead to this suggestion?)

_____

_____

_____

_____

Suggestions for improvement:

_____

_____

_____

_____

_____

BARRX Medical Review (For internal Use Only):

_____

_____

_____

Decision: ☐ Design Input (List project name) _____
☐ CAR (List CAR#) _____
☐ Labeling changes (List ECO#) _____

Approved By: _____ Date: _____